IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Morteza Naghavi	§		
		§		
Serial No:	10/645,970	§	Group Art Unit:	3768
		§		
Filed:	08/22/2003	§	Examiner:	Jennifer A Horwat
		§		
For:	Novel Risk Assessment Method	§	Attorney Docket:	D8562-14
	Based Upon Coronary Calcification	§		
	Distribution Pattern Imaged By	§		
	Computed Tomography	§		

DECLARATION UNDER 37 CFR § 1.131

We, S. Ward Casscells and James T. Willerson, hereby declare as follows:

1. We are named inventors of this patent application.

2. We understand that claims 1, 3-12, 14, 17, 19-26, and 31-34 were rejected under 35 U.S.C. §102(e) as being anticipated by Iatrou, United States Patent Publication 2004/0136491.

3. This Declaration is being submitted to swear behind Iatrou, to disqualify it as prior art under 35 U.S.C. 102(e)/103 with respect to the claims identified in paragraph 2 above.

4. The earliest priority date for Iatrou et al. is July 23, 2002.

5. Before July 23, 2002, we conceived the methods and systems set forth in claims 1, 3-12, 14, 17, 19-26, and 31-34 of this application.

6. Prior to July 23, 2002, we conceived the method of assessing coronary risk based upon coronary calcification claimed in claim 1 and its dependent claims.

7. Prior to July 23, 2002, we conceived the method of assessing coronary risk based upon coronary calcification claimed in claim 17 and its dependent claims.

8. Prior to July 23, 2002, we conceived the system for assessing coronary risk based upon coronary calcification claimed in claim 31 and its dependent claims.

9.   Attached as Exhibit A is an invention disclosure document that was provided to our patent attorneys for the purpose of drafting the present patent application. The disclosure describes a system for assessing coronary risk based upon coronary calcification, comprising a scanner adapted to detect a characteristic of a region of interest in a patient; a data store operatively coupled to the scanner and adapted to receive and store data generated by the scanner; and a data analyzer operatively coupled to the data store, wherein the data analyzer further comprises a scoring module adapted to determine distribution of the scanned characteristic of the region of interest in the patient.

10.   Exhibit A further describes a method of assessing coronary risk based upon coronary calcification, comprising scanning a region of interest in a patient using computed tomography (CT); storing CT generated data resulting from said scanning, the data comprising calcification data related to calcification of a blood vessel; generating scoring data representative of a statistical distribution of calcification in the blood vessel using the calcification data; and assessing the patient's risk of cardiovascular disease using the scoring data.

11.   Exhibit A further describes A method of assessing coronary risk based upon coronary calcification, comprising: scanning a region of interest in a patient using computed tomography (CT); storing CT generated data resulting from said scanning, the data comprising calcification data: analyzing the data to determine a distribution of calcification in the patient; and assessing the patient's risk of cardiovascular disease based upon said analyzing.

12.   From prior to July 23, 2002 until our filing date of August 22, 2003, we and our attorneys worked diligently to complete the filing of a patent application covering this invention.

13. Prior to August 22, 2003, we received a draft of the patent application, which incorporated the invention of claims 1, 3-12, 14-17, 19-26, and 31-34, including the subject matter we had disclosed in Exhibit A.

14. On August 22, 2003, our patent attorneys filed the application in the Patent and Trademark Office.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

DATE: 16 Nov 2006
Cascells S. Ward

DATE: 11/21/06
Willie ___

James T. Williams

THE UNIVERSITY *of* TEXAS

HEALTH SCIENCE CENTER AT HOUSTON

INVENTION DISCLOSURE FORM

File #:

1. INVENTOR(S) INFORMATION

Name/Degrees	Title	School	Department
Ward Casscells, MD	Professor of medicine	Medical School	Int. Med./Cardiology
James T. Willerson, MD	Professor of medicine	Medical School	Int. Med./Cardiology
Morteza Naghavi, MD	Assistant Professor	Medical School	Int. Med./Cardiology
Alireza Zarrabi, MD	Research Associate	Medical School	Int. Med./Cardiology

2. Percent time employed at UTHSCH: **100%**
3. Other Employment/Appointments, if any: **Texas Heart Institute**
4. For more than one inventor, is there in existence a royalty sharing agreement? **No**

5. THE INVENTION:

(a) Descriptive title of Invention:

A Novel Risk Assessment Method based on Coronary Calcification Distribution Pattern Imaged by Computed Tomography

(b) Invention Type:
__ Device ___Drug __X_Method ___Composition ____ X_Software ___Other

Attach a layman's description of the invention. Be as specific as possible and address the following points:

(c) Summarize the purpose and use of the invention

In this method instead of using calcium score for risk assessment in patients, we are suggesting to use of statistical data that can be took out from the primary score to predict clinical outcome.

The current "calcium score" is an estimate of total amount of calcium accumulated in coronary arteries. Calcium scoring determines if the arteries have too much calcium (part of atherosclerotic plaque that restricts the amount of blood) but can not clearly shows plaque burden and plaque progression process.

In this method we show different distribution of coronary calcification detected by CAT scan including proximal versus distal artery calcification, distribution of calcification in different coronary branches, concentric calcification versus eccentric calcification, abrupt changes in calcification density, and size of the plaque inn calcified area. For all of these data we calculate different variables (mean, median, mode, standard deviation (SD), range, coefficient of variation, skewness, kurtosis, and other statistical parametes).

Abrupt changes in regional coronary elasticity, like abrupt changes in density, should be high-risk regions.

In this method we also measure the density of the calcification in specific area and show the relation of different densities in each place to the outcome of lesion.

By collecting all of these data and multivariate analysis this method can map the coronary arteries in to multiple sections which each part has its specificity related to calcification.

(d) Novelty and non-obviousness of the invention

The traditional coronary calcium scoring system does not include any information regarding the distribution pattern of calcified areas and their anatomical position in relation to coronary tree.

This method lacks high specificity for prediction of outcome and there has not been widely accepted.

However, our proposed method for the first time describes the risk of coronary events and progression of atherosclerotic plaque (changing of plaque burden) through calcification distribution which is detected by CAT scan.

(e) Similar inventions currently in use

Calcium scoring estimate subject's cardiovascular risk and evaluate progressive accumulation of calcium as a marker for arterial blockages.

EBT Calcium Score Range (% diameter stenosis)	Angiographic Disease Severity
27-88	>20%
89-127	>30%
128-166	>40%
167-370	>50%
>371	>70%

The above traditional scoring system does not include any information regarding the site of calcification

The current method suffers from poor specificity to predict coronary outcome.

(f) Advantages of invention over current practice

In current scoring system, some people who have very high scores would be free of clinical heart disease, while others may have low scores and have suffered a major heart attack. The calcium score is a more direct estimate of the amount of plaque present in the arteries than are the risk factors.

The present method is able to show the progression of plaque and assess the risk of coronary events according to multiple variables mined from plaque calcification.

(g) A list of potential claims of the invention

Relation of distribution of calcification in proximal part of coronary arteries with risk of coronary events vs. distal distribution.

Relation of eccentric plaque calcification with risk of coronary events vs. concentric calcification.

(h) State of development of the invention

In human

6. CONCEPTION AND DEVELOPMENT OF THE INVENTION
(a) Date invention was conceived: **May 2002**
(b) Date the first drawing or sketch was made: **May 2002**
(c) Date first construction or model was made: **May 2002**

ATTACH SUPPORTING MATERIALS (DATA, DRAWINGS, PHOTOS, FORMULAS, ETC.)

(d) Approximate time spent by you, personally, in making the invention?
(e) Was any of this work performed at UTHSCH? _X_Yes __No
   If no, is it your intent to assign this invention to UTHSCH? __ Yes ___No
(f) Were any of the following used in the development of the invention:
   UTHSCH Facilities or Technical Support :(Laboratories, offices, personnel, etc.) ___Yes___No
   UTHSCH Equipment: (tools, machinery, etc.) ___Yes __No
   UTHSCH Materials: (Supplies, etc.; if scrap waste, or salvage materials were used, give estimated value of materials.)
   ___Yes__No   Estimated dollar value: $___
(g) Estimated amount of UTHSCH funds, other than salaries and wages, which were actually obligated or expended for the purpose of   making the invention: $
__

(h) Contribution of time or services of other UTHSCH employees (state approximate number of hours and type of assistance):
___Yes__ No _____

7. DISCLOSURE:

(a) Has the invention been, or will it be disclosed or described in any manner (publication, abstracts, World Wide Web, oral presentation, etc.)? _Yes _X No ; If yes, answer (b), (c) and (d), below
(b) Date invention was first disclosed to others:
(c) To whom was invention disclosed:
(d) Date of the first written disclosure:
(e) Has the invention been tested? ____Yes __No; If yes: ___experimentally ___routinely
If yes, give date and results test: Date: ___
Details:___

8. PRIOR ART: Please provide a list and copies of all known related publications and patents. **Attached.**

The following are World Wide Web sites that may be used for patent searching. You are encouraged to conduct a preliminary search and submit your findings along with the disclosure.

http://autm.net/	Assoc. of University Technologies Managers
http://www.uspto.gov/	US PTO
http://www.delphion.com/	Delphion
http://sunsite.unc.edu/patents/intropat.html	STO's Internet Patent Search System
http://www.micropat.com/	MicroPatent
http://www.qpat.com/	Qpat-US

9. COMMERCIALIZATION:

Please address the potential commercialization of the invention as follows:
(a) Commercial possibilities/value of the invention/

(b) A list of potential licensees or research sponsors

(c) Attach an abstract of the invention

Dr. James T. Willerson

| Signature *(signed)* | Date 7/8/02 |
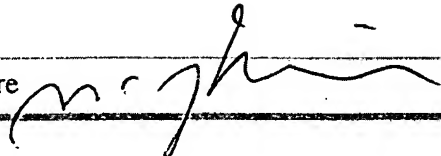
Complete Mailing Address (required)	
HOME	**WORK**
3314 Georgetown	7000 Fannin UCT 1707
Houston, Texas 77030	Houston, Texas 77030
Phone	Phone 713.500-3000

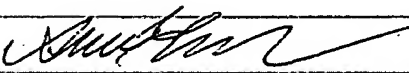Dr. S. Ward Casscells

| Signature | Date |

Complete Mailing Address (required)	
HOME	**WORK**
3402 Wickersham Lane,	6431 Fannin MSB 1.254
Houston Tx 77027	Houston, TX 77030
Phone	Phone 713-500-6545

Dr. Morteza Naghavi

Signature _(signature)_ Date 7-8-02

Complete Mailing Address (required)	
HOME	**WORK**
3525 Sage #1405	6431 Fannin, MSB-1.246
Houston, TX 77056	Houston, TX 77030
Phone	Phone 832-355-9138

Dr. Alireza Zarrabi

Signature _(signature)_ Date 7-8-02

HOME	**WORK**
Alireza Zarrabi	Alireza Zarrabi, MD
10225 Wortham Blvd. Apt.# 17206 Houston, TX 77065	6770 Bertner MB 3-277 Houston, TX 77030
Phone:	Phone: 832-355-9136